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DICKSTEIN SHAPIRO LLP			NAJARIAN, LENA	
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Washington, DC 20006-5403			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/981,752	SCHMIEDING, REINHOLD
	<b>Examiner</b>	<b>Art Unit</b>
	LENA NAJARIAN	3686

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 October 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 and 17-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Notice to Applicant***

1. This communication is in response to the amendment filed 10/29/08. Claims 1, 8, 14, and 18-24 have been amended. Claims 1-15 and 17-24 remain pending.

### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 1-17 & 19-24 under 35 U.S.C. 112, second paragraph, is hereby withdrawn due to the amendment filed 10/29/08.

### ***Claim Rejections - 35 USC § 101***

3. The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-15 and 17-24 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-15 and 17-24 fail to satisfy the requirements for statutory subject matter eligibility because they are considered to preempt the underlying abstract idea, since they would foreclose others from substantially *all* practical applications of the same abstract idea. It has been held that such claims are considered to be unpatentable for comprising non-statutory subject matter. *In re Schrader*, 22 F.3d 290, 295; 30 USPQ2d 1455, 1459 (Fed. Cir. 1994). See MPEP § 2106(IV).

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 18, 21, 23, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Bradbury et al. (US 2002/0007294 A1).

(A) Referring to claim 18, Bradbury discloses a method of providing a service, comprising (para. 64 of Bradbury):

receiving at a service provider specifications and conditions of a patient from a medical provider prior to said patient undergoing a predetermined surgical procedure (para. 52, para. 15, and Fig. 2 of Bradbury);

delivering an allograft to said medical provider, the delivering of the allograft being arranged by said service provider, said allograft being selected based on said specifications and conditions of said patient and also based on said predetermined surgical procedure (para. 15 and para. 13 of Bradbury); and

delivering surgical instrumentation for performing said predetermined surgical procedure, the delivering of the surgical instrumentation being arranged by said service provider (para. 28 of Bradbury).

(B) Referring to claim 21, Bradbury discloses wherein said act of delivering an allograft comprises customizing said allograft based on said specifications and conditions of said patient (para. 8 of Bradbury).

(C) Referring to claim 23, Bradbury discloses wherein said act of delivering an allograft further comprises said service provider delivering said allograft to said medical provider (para. 15 of Bradbury).

(D) Referring to claim 24, Bradbury discloses wherein said act of delivering surgical instrumentation further comprises said service provider delivering said surgical instrumentation to said medical provider (para. 28 of Bradbury).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application.

(A) Referring to claim 1, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

providing the predetermined specifications and conditions of the patient to a central site (Fig. 2 and para. 52 of Bradbury);

subsequently customizing an allograft to be used in a predetermined surgical procedure, the allograft being customized to the predetermined specifications and conditions of the patient and of the predetermined surgical procedure to be performed on the patient (para. 8 of Bradbury); and

coordinating, by the service provider, delivery of the customized allograft to the medical provider (para. 15 of Bradbury).

Bradbury does not expressly teach that the customizing is done *at a tissue bank*. Bradbury does disclose providing, by the service provider, graft specific surgical instrumentation to match the specifications of the allograft and the procedure (para. 28 of Bradbury). However, Bradbury does not disclose *loaning* the instrumentation.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The

motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

Admission discloses loaning the surgical instrumentation (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing for a specified time period the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(B) Referring to claim 8, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

providing the predetermined specifications and conditions of the patient to a central site (Fig. 2 and para. 52 of Bradbury);

arranging, by the service provider, for delivery of a customized allograft for a predetermined surgical procedure, the customized allograft being sized according to the specifications and conditions of the patient and of the predetermined surgical procedure (para. 8 and para. 15 of Bradbury);

customizing, by the service provider, a surgical instrumentation kit specifically designed for use with the customized allograft and for performing the predetermined surgical procedure (para. 28 of Bradbury), and

providing, by the service provider, the customized surgical instrumentation kit to the medical provider for the performance of the surgical procedure (para. 28 of Bradbury).

Bradbury does not expressly disclose that the allograft is sized by a tissue bank and that the service provider loans the surgical instrumentation.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

Admission discloses loaning the surgical instrumentation (p. 1, lines 12-19 of Specification).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the feature of loaning surgical instrumentation with the motivation of providing, for a specific amount of time, the appropriate instruments if the surgeon or medical facility does not already own the necessary instrumentation (p. 1, lines 12-19 of Specification).

(C) Claims 2-4 and 9-10 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

9. Claims 5-6 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of Ramshaw et al. (5,791,907).

(A) Claims 5-6 and 11-12 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

10. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), in view of Applicant's admitted prior art (admission) given in "Brief Description of the Related Art" section of application, and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) Claims 7 and 13 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

11. Claims 14, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Filho (6,089,867), and further in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 14, Bradbury discloses a method of providing a customer-oriented integrated product and service package for a surgical procedure, comprising (para. 64 of Bradbury):

providing predetermined specifications and conditions of a patient from a medical provider to a service provider (Fig. 2, para. 7, and para. 15 of Bradbury);

providing the predetermined specifications and conditions of the patient to a central site (Fig. 2 and para. 52 of Bradbury);

customizing and sizing an allograft according to the specifications and conditions of the patient and of a predetermined surgical procedure (para. 8 of Bradbury);

arranging, by the service provider, for delivery of the customized allograft for the predetermined surgical procedure to a medical facility at which the predetermined surgical procedure is to be performed (para. 15 of Bradbury);

Bradbury does not expressly disclose that the customizing and sizing of an allograft is done at a *tissue bank*.

Filho discloses receiving the implant from a tissue bank (col. 3, lines 46-53 and col. 4, lines 20-22 of Filho).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Filho within Bradbury. The

motivation for doing so would have been to provide an appropriate place for the storage of the implants (col. 3, lines 46-53 of Filho).

While Bradbury does disclose providing customer support (see para. 63-64 of Bradbury), Bradbury and Filho do not expressly disclose providing, by the service provider, technical support and/or customer support to operating personnel before and/or during performance of the predetermined surgical procedure at the medical facility; and prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure.

Ramshaw discloses providing, by the service provider, technical support and/or customer support to operating personnel before and/or during the performance of the predetermined surgical procedure at the medical facility (col. 2, lines 39-56 and col. 1, lines 12-24 of Ramshaw) and prior to the time the surgical procedure is to be performed, providing training to operating personnel in the use of the instruments and skills to perform the surgical procedure (abstract and col. 10, lines 32-61 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury and Filho. The motivation for doing so would have been to ensure the proper and safe performance of the surgical procedures (col. 1, lines 43-48 of Ramshaw).

(B) Claims 15 and 17 have not been amended and are therefore rejected for the same reasons given in the previous Office Action, and incorporated herein.

12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Ramshaw et al. (5,791,907).

(A) Referring to claim 22, Bradbury does not disclose arranging, by said service provider, provision of technical support to said medical provider for performing said predetermined surgical procedure.

Ramshaw discloses providing technical support to said medical provider for performing said predetermined surgical procedure (col. 1, lines 12-24 and 49-65 of Ramshaw).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Ramshaw within Bradbury. The motivation for doing so would have been to have a qualified instructor or proctor present to instruct the user (col. 1, lines 12-24 and col. 15, lines 13-17 of Ramshaw).

13. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bradbury et al. (US 2002/0007294 A1) in view of Hoemann et al. (US 2002/0082220 A1).

(A) Referring to claims 19 and 20, Bradbury discloses wherein said act of delivering an allograft comprises delivering an implant to said medical provider (para. 15 of Bradbury).

Bradbury does not disclose that the implant is a meniscus allograft and a osteochondral allograft.

Hoemann disclose meniscus and osteochondral allografts (para. 3 and para. 12 of Hoemann).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the features of Hoemann within Bradbury. The motivation for doing so would have been for the service to accommodate various types of allografts.

***Response to Declaration Under 37 CFR 1.131***

14. The declaration filed on 4/30/08 under 37 CFR 1.131 has been considered but is ineffective to overcome the Bradbury reference.

To establish prior invention of the claimed subject matter, applicant can provide a showing of facts sufficient to show: (1) conception of the invention prior to the effective date of the reference; coupled with, (2) due diligence from prior to the date of the reference, through to the (3) filing date of the application (constructive reduction to practice). See MPEP § 715.07(III).

Applicant's showing of facts is sufficient to establish the first and third of these three criteria, the date of conception of the invention and the date of constructive reduction to practice.

However, applicant has failed to satisfy the second of the three necessary criteria, because the evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Bradbury reference to either a constructive reduction to practice or an actual reduction to practice.

Where, as here, conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to *allege* that applicant or patent owner had been diligent. *Ex parte Hunter*, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of *facts* establishing diligence. Merely stating that the subject matter "was diligently reduced to practice" has been held to be not a showing but a mere pleading. *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964). Note that applicant must account for the *entire period* during which diligence is required. *Gould v. Schawlow*, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966). Even a two-day period lacking activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue). See MPEP §§ 715.07(a) and 2138.06.

Additionally, note that the requirement for a showing of diligence applies to both *engineering* work on the invention *per se* as well as to *legal* work by any attorneys involved in preparing, or assisting in preparing, a patent application. See MPEP §§ 715.07(a) and 2138.06.

***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches materials and methods for improved bone tendon bone transplantation (US 6,497,726 B1).

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571)

272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/L. N./  
Examiner, Art Unit 3686  
In  
12/31/08

/Gerald J. O'Connor/  
Supervisory Patent Examiner  
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